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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,929	04/02/1999	JURGEN KLEINSCHMIDT	4121-107	3634

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EXAMINER
WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.	Applicant(s)
09/230,929	Kleinschmidt, J. et al.
Examiner	**Art Unit**
Joseph T. Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED *Feb 6, 2002* FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

a) [X] The period for reply expires *3* months from the mailing date of the final rejection.

b) [ ] In view of the early submission of the proposed reply (within two months as set forth in MPEP § 706.07 (f)), the period for reply expires on the mailing date of this Advisory Action, OR continues to run from the mailing date of the final rejection, whichever is later. In no event, however, will the statutory period for the reply expire later than SIX MONTHS from the mailing date of the final rejection.

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. [ ] A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. [ ] The proposed amendment(s) will be entered upon the timely submission of a Notice of Appeal and Appeal Brief with requisite fees.

3. [X] The proposed amendment(s) will not be entered because:

   (a) [X] they raise new issues that would require further consideration and/or search. (See NOTE below);

   (b) [X] they raise the issue of new matter. (See NOTE below);

   (c) [ ] they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) [ ] they present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: *See attached.*

4. [ ] Applicant's reply has overcome the following rejection(s):

5. [ ] Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claim(s).

6. [X] The a) [ ] affidavit, b) [ ] exhibit, or c) [X] request for reconsideration has been considered but does NOT place the application in condition for allowance because:
   See attached.

7. [ ] The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

8. [X] For purposes of Appeal, the status of the claim(s) is as follows (see attached written explanation, if any):

   Claim(s) allowed: _____

   Claim(s) objected to: _____

   Claim(s) rejected: *14-66*

9. [ ] The proposed drawing correction filed on _____ a) [ ] has b) [ ] has not been approved by the Examiner.

10. [ ] Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

11. [ ] Other:

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Attachment to Advisory Action:

Section 3(a):

There recitation of 'the non-transforming ORF' lacks antecedent basis and would raise 35 USC 122, second, paragraph issues. The amendments contain containing new proposed limitations to the fusion protein do not have literal support nor specific figurative support toward the broad embodiment in the instant specification, and raise issues of new matter. Further, the previous claims encompassed a fusion polypeptide, and no clear link of how or what was comprised within said polypeptide fusion protein. The new structural limitations would require a new search and further consideration.

Section 6(c):

Applicants arguments directed to the obviousness of the invention encompassing a specific single fusion HPV protein in the combination of Donnelly *et al.* and Johnson references alone is convincing. Specifically, while each reference teaches that multiple epitopes or multi-valent responses could be used in DNA vaccines, Examiner agrees that the generation of one polypeptide containing multiple domains is not specifically taught in either reference. However, the instant claims can fairly be interpreted to encompass fusion proteins of the ORFs or fragments thereof. A 'fusion polypeptide' is *referred* to as polypeptides which 'can be present in any combination'(page 5; last full paragraph), however it does not require that a fusion protein contain both L- and E-ORFs. In addition, Applicants' arguments directed to the subsequent

rejections which include specific teaching of multi-epitope fusion proteins, such as Whittle *et al.*, Stanley *et al.* and Gissmann *et al.* is not found convincing. Donnelly *et al.* is relied upon for the teaching that multiple epitopes of HPV can be used in DNA vaccines. Each Donnelly *et al.* and Johnson acknowledge the same limitations of know vectors taught in the art for DNA vaccines, and Johnson is relied upon for the teaching of an improved vector system, rAAV vectors, for the deliver and expression of a gene of interest, in particular for use in DNA vaccines. Whittle *et al.*, Stanley *et al.* and Gissmann *et al.* clearly teach that fusion proteins could be generated from recombinant vectors, and Whittle *et al.* and Stanley *et al.* specifically teach that they can be used in immunotherapeutic methods. In view of the art as a whole, it is maintained that the combination of the teachings in the cited references as a whole provide adequate motivation and guidance which makes obvious the instantly claimed products.